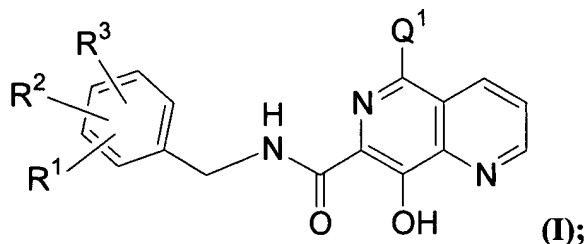


IN THE CLAIMS

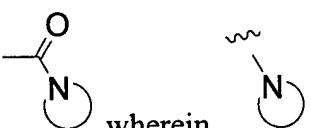
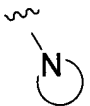
The listing of the claims which follows replaces any and all prior versions and/or listings of the claims in the application.

1. (original) A pharmaceutical composition comprising a therapeutically effective amount of a compound of Formula (I), or a pharmaceutically acceptable salt thereof:



and a nonionic surfactant; wherein in Formula (I) each of R<sup>1</sup>, R<sup>2</sup> and R<sup>3</sup> is independently:

- (1) -H,
- (2) -C<sub>1-6</sub> alkyl, optionally substituted with one substituent which is -OH, -O-C<sub>1-6</sub> alkyl, -O-C<sub>1-6</sub> haloalkyl, -CN, -NO<sub>2</sub>, -N(R<sup>a</sup>R<sup>b</sup>), -C(=O)N(R<sup>a</sup>R<sup>b</sup>), -C(=O)R<sup>a</sup>, -CO<sub>2</sub>R<sup>c</sup>, -OCO<sub>2</sub>R<sup>c</sup>, -S(O)<sub>n</sub>R<sup>c</sup>, -SO<sub>2</sub>N(R<sup>a</sup>R<sup>b</sup>), -N(R<sup>a</sup>)C(=O)R<sup>b</sup>, -N(R<sup>a</sup>)CO<sub>2</sub>R<sup>c</sup>, -N(R<sup>a</sup>)SO<sub>2</sub>R<sup>c</sup>, -N(R<sup>a</sup>)SO<sub>2</sub>N(R<sup>a</sup>R<sup>b</sup>), -OC(=O)N(R<sup>a</sup>R<sup>b</sup>), or -N(R<sup>a</sup>)C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (3) -O-C<sub>1-6</sub> alkyl, optionally substituted with one substituent which is -OH, -O-C<sub>1-6</sub> alkyl, -O-C<sub>1-6</sub> haloalkyl, -S(O)<sub>n</sub>R<sup>c</sup>, -N(R<sup>a</sup>)-CO<sub>2</sub>R<sup>c</sup>, -C(=O)N(R<sup>a</sup>R<sup>b</sup>), -SO<sub>2</sub>N(R<sup>a</sup>R<sup>b</sup>), -N(R<sup>a</sup>)C(=O)R<sup>b</sup>, -N(R<sup>a</sup>)CO<sub>2</sub>R<sup>c</sup>, -N(R<sup>a</sup>)SO<sub>2</sub>R<sup>c</sup>, -N(R<sup>a</sup>)SO<sub>2</sub>N(R<sup>a</sup>R<sup>b</sup>), -OC(=O)N(R<sup>a</sup>R<sup>b</sup>), or -N(R<sup>a</sup>)C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (4) -C<sub>1-6</sub> haloalkyl,
- (5) -O-C<sub>1-6</sub> haloalkyl,
- (6) -OH,
- (7) halo,
- (8) -NO<sub>2</sub>,
- (9) -CN,
- (10) -C(=O)R<sup>a</sup>,
- (11) -CO<sub>2</sub>R<sup>c</sup>,
- (12) -S(O)<sub>n</sub>R<sup>c</sup>,
- (13) -SO<sub>2</sub>N(R<sup>a</sup>R<sup>b</sup>),
- (14) -N(R<sup>a</sup>R<sup>b</sup>),
- (15) -C(=O)N(R<sup>a</sup>R<sup>b</sup>),

- (16)  wherein  is azetidiny, pyrrolidinyl, piperidinyl, or morpholino,
- (17) -N(R<sup>a</sup>)SO<sub>2</sub>R<sup>c</sup>,
- (18) -OC(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (19) -N(R<sup>a</sup>)C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (20) -N(R<sup>a</sup>)-C<sub>1-6</sub> alkyl-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (21) -N(R<sup>a</sup>)-C<sub>1-6</sub> alkyl-SR<sup>a</sup>,
- (22) -N(R<sup>a</sup>)-C<sub>1-6</sub> alkyl-OR<sup>a</sup>,
- (23) -N(R<sup>a</sup>)-C<sub>1-6</sub> alkyl-N(R<sup>a</sup>)<sub>2</sub>,
- (24) -N(R<sup>a</sup>)-C<sub>1-6</sub> alkyl-N(R<sup>a</sup>)-C(R<sup>a</sup>)=O,
- (25) -N(R<sup>a</sup>)-C(=O)-C<sub>1-6</sub> alkyl-N(R<sup>a</sup>R<sup>b</sup>),
- (26) -N(R<sup>a</sup>)C(=O)-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (27) -OCO<sub>2</sub>R<sup>c</sup>,
- (28) -N(R<sup>a</sup>)-SO<sub>2</sub>N(R<sup>a</sup>R<sup>b</sup>),
- (29) -N(R<sup>a</sup>)-SO<sub>2</sub>-C<sub>1-6</sub> alkyl-N(R<sup>a</sup>R<sup>b</sup>),
- (30) -N(R<sup>a</sup>)C(=O)R<sup>b</sup>,
- (31) -N(R<sup>a</sup>)CO<sub>2</sub>R<sup>c</sup>,
- (32) -S-C<sub>1-6</sub> alkyl-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (33) -N(SO<sub>2</sub>R<sup>c</sup>)-C<sub>1-6</sub> alkyl-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (34) -N(R<sup>a</sup>)-C(=O)-C<sub>1-6</sub> alkyl-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (35) -N(R<sup>a</sup>)-C(=O)-C<sub>1-6</sub> alkyl-N(R<sup>a</sup>)C(=O)(R<sup>b</sup>),
- (36) -N(R<sup>a</sup>)-SO<sub>2</sub>-C<sub>1-6</sub> alkyl-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (37) -N(R<sup>a</sup>)-SO<sub>2</sub>-C<sub>1-6</sub> alkyl-N(R<sup>a</sup>)C(=O)(R<sup>b</sup>),
- (38) -C(=O)N(R<sup>a</sup>)-C<sub>1-6</sub> alkyl-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (39) -C(=O)N(R<sup>a</sup>)-C<sub>1-6</sub> alkyl-N(R<sup>a</sup>)C(=O)(R<sup>b</sup>), with the proviso that the -N(R<sup>a</sup>)- moieties are not both attached to the same carbon atom of the -C<sub>1-6</sub> alkyl- moiety,
- (40) -C(=O)N(R<sup>a</sup>)-C<sub>1-6</sub> alkyl-O-C<sub>1-3</sub> alkyl, with the proviso that the -N(R<sup>a</sup>)- moiety and the -O-C<sub>1-3</sub> alkyl group are not both attached to the same carbon atom of the -C<sub>1-6</sub> alkyl- moiety, or
- (41) -C(=O)N(R<sup>a</sup>)-C<sub>1-6</sub> alkyl-S(O)<sub>n</sub>R<sup>c</sup>;

Q<sup>1</sup> is:

- (1) -H,
- (2) -C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (3) -C<sub>1-6</sub> alkyl-C(=O)N(R<sup>a</sup>R<sup>b</sup>),

- (4) -S-C<sub>1-6</sub> alkyl-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (5) -O-C<sub>1-6</sub> alkyl-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (6) -N(R<sup>a</sup>)-C(R<sup>b</sup>)=O,
- (7) -N(SO<sub>2</sub>R<sup>c</sup>)-C<sub>1-6</sub> alkyl-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (8) -N(R<sup>a</sup>)-C(=O)-C(=O)-N(R<sup>a</sup>R<sup>b</sup>),
- (9) -N(R<sup>a</sup>)SO<sub>2</sub>R<sup>c</sup>,
- (10) -SO<sub>2</sub>N(R<sup>a</sup>R<sup>b</sup>),
- (11) -CH=CH-C(=O)-N(R<sup>a</sup>R<sup>b</sup>),
- (12) -N(R<sup>a</sup>)-C<sub>1-6</sub> alkyl-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (13) -N(R<sup>a</sup>)-C(=O)-N(R<sup>a</sup>R<sup>b</sup>),
- (14) -HetC,
- (15) -C<sub>1-6</sub> alkyl-HetC, or
- (16) -N(R<sup>a</sup>)-C<sub>1-6</sub> alkyl-HetC;

HetC is a 5- to 7-membered saturated heterocyclic ring containing from 1 to 4 heteratoms independently selected from N, O and S, wherein the saturated heterocyclic ring is optionally substituted with from 1 to 4 substituents each of which is independently halogen, -C<sub>1-4</sub> alkyl, -C<sub>3-6</sub> cycloalkyl, -O-C<sub>1-4</sub> alkyl, -C<sub>1-4</sub> haloalkyl, -O-C<sub>1-4</sub> haloalkyl, -CN, oxo, phenyl, benzyl, phenylethyl, -(CH<sub>2</sub>)<sub>0-3</sub>C(=O)N(R<sup>a</sup>R<sup>b</sup>), -(CH<sub>2</sub>)<sub>0-3</sub>C(=O)R<sup>a</sup>, -N(R<sup>a</sup>)-C(=O)R<sup>b</sup>, N(R<sup>a</sup>)-CO<sub>2</sub>R<sup>c</sup>, -(CH<sub>2</sub>)<sub>1-3</sub>N(R<sup>a</sup>)-C(=O)R<sup>b</sup>, -N(R<sup>a</sup>R<sup>b</sup>), -(CH<sub>2</sub>)<sub>1-3</sub>N(R<sup>a</sup>R<sup>b</sup>), -SO<sub>2</sub>R<sup>c</sup>, -(CH<sub>2</sub>)<sub>0-3</sub>C(=O)-HetD, -HetD, -N(R<sup>a</sup>)-HetD, and -(CH<sub>2</sub>)<sub>1-3</sub>-HetD; wherein each HetD is independently a 5- or 6-membered heteroaromatic ring containing from 1 to 4 nitrogen atoms or a 5- or 6-membered saturated heterocyclic ring containing from 1 to 4 nitrogen atoms, wherein the ring is optionally substituted with 1 or 2 substituents each of which is independently halogen, oxo, -C<sub>1-4</sub> alkyl, or -O-C<sub>1-4</sub> alkyl;

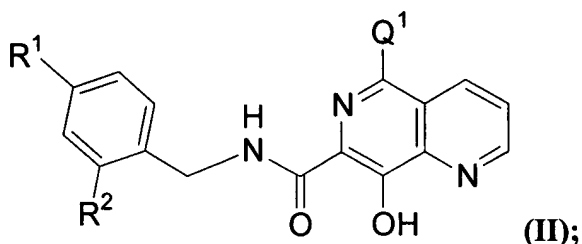
each R<sup>a</sup> is independently -H, -C<sub>1-6</sub> alkyl, -C<sub>1-6</sub> haloalkyl, or -C<sub>3-6</sub> cycloalkyl;

each R<sup>b</sup> is independently -H, -C<sub>1-6</sub> alkyl, -C<sub>1-6</sub> haloalkyl, or -C<sub>3-6</sub> cycloalkyl;

each R<sup>c</sup> is independently -C<sub>1-6</sub> alkyl, -C<sub>1-6</sub> haloalkyl, or -C<sub>3-6</sub> cycloalkyl; and

each n is independently an integer equal to zero, 1, or 2.

2. (original) The pharmaceutical composition according to claim 1, wherein the compound is a compound of Formula (II) or a pharmaceutically acceptable salt thereof:



and a nonionic surfactant; wherein in Formula (II) each of R<sup>1</sup> and R<sup>2</sup> is independently:

- (1) -H,
- (2) -C<sub>1-4</sub> alkyl,
- (3) -(CH<sub>2</sub>)<sub>1-3</sub>-C(=O)N(R<sup>a</sup>R<sup>b</sup>),
- (4) -(CH<sub>2</sub>)<sub>1-3</sub>-N(R<sup>a</sup>R<sup>b</sup>),
- (5) -(CH<sub>2</sub>)<sub>1-3</sub>-CO<sub>2</sub>R<sup>c</sup>,
- (6) -(CH<sub>2</sub>)<sub>1-3</sub>-S(O)<sub>n</sub>R<sup>c</sup>,
- (7) -(CH<sub>2</sub>)<sub>1-3</sub>-SO<sub>2</sub>N(R<sup>a</sup>R<sup>b</sup>),
- (8) -O-C<sub>1-4</sub> alkyl,
- (9) -CF<sub>3</sub>,
- (10) -OCF<sub>3</sub>,
- (11) halo selected from -F, -Cl, and -Br,
- (12) -CO<sub>2</sub>R<sup>c</sup>,
- (13) -S(O)<sub>n</sub>R<sup>c</sup>,
- (14) -SO<sub>2</sub>N(R<sup>a</sup>R<sup>b</sup>),
- (15) -N(R<sup>a</sup>R<sup>b</sup>), or
- (16) -C(=O)N(R<sup>a</sup>R<sup>b</sup>);

with the proviso that at least one of R<sup>1</sup> and R<sup>2</sup> is not -H;

Q<sup>1</sup> is -H, -C(=O)N(R<sup>a</sup>R<sup>b</sup>), -N(R<sup>a</sup>)SO<sub>2</sub>R<sup>c</sup>, or 1,1-dioxido-1,2-thiazinan-2-yl;

each R<sup>a</sup> is independently -H, -C<sub>1-4</sub> alkyl, or cyclopropyl;

each R<sup>b</sup> is independently -H, -C<sub>1-4</sub> alkyl, or cyclopropyl; and

each R<sup>c</sup> is independently a -C<sub>1-4</sub> alkyl or cyclopropyl.

3. (original) The pharmaceutical composition according to claim 2, wherein the compound of Formula (II) is Compound A or a sodium salt of Compound A, wherein Compound A is 5-(1,1-dioxido-1,2-thiazinan-2-yl)-N-(4-fluorobenzyl)-8-hydroxy-1,6-naphthyridine-7-carboxamide.

4. (currently amended) The pharmaceutical composition according to claim 1, ~~any one of claims 1 to 3~~, wherein the nonionic surfactant is present in an amount of at least about 0.1 wt. %

5. (currently amended) The pharmaceutical composition according to claim 1, ~~any one of claims 1 to 4~~, wherein the nonionic surfactant comprises a poloxamer.

6. (currently amended) The pharmaceutical composition according to claim 1, ~~any one of claims 1 to 5~~, wherein the composition is encapsulated.

7. (original) The pharmaceutical composition according to claim 6, wherein the encapsulated composition is a granulated composition further comprising a disintegrant, optionally a diluent, optionally a binder, optionally a lubricant, and optionally an antioxidant.

8. (original) The pharmaceutical composition according to claim 6, wherein the compound in the encapsulated composition is Compound A or a sodium salt thereof; and the encapsulated composition further comprises a disintegrant.

9. (currently amended) The pharmaceutical composition according to claim 1, ~~any one of claims 1 to 5~~, wherein the composition is compressed into a tablet.

10. (original) The pharmaceutical composition according to claim 9, wherein the compressed tablet further comprises a diluent, a disintegrant, a lubricant, optionally a binder, and optionally an antioxidant.

11. (original) The pharmaceutical composition according to claim 9, wherein the compound in the compressed tablet is Compound A or a sodium salt thereof; and the compressed tablet further comprises diluent A, a disintegrant, and a lubricant.

12. (original) The pharmaceutical composition according to claim 9, wherein the compound in the compressed tablet is Compound A or a sodium salt thereof; and the compressed tablet further comprises a diluent, a disintegrant, a lubricant, and a stabilizing agent.

13. (original) The encapsulated composition according to claim 7, wherein:

the compound is Compound A or a sodium salt thereof;

the nonionic surfactant comprises a poloxamer or a polysorbate;

the disintegrant comprises croscarmellose sodium, crospovidone, povidone, or sodium starch glycolate;

the optional diluent comprises lactose, microcrystalline cellulose, mannitol, anhydrous dibasic calcium phosphate, dibasic calcium phosphate dihydrate, or a combination of any two of the foregoing;

the optional binder comprises hydroxypropyl cellulose, hydroxypropyl methylcellulose, or povidone;

the optional lubricant comprises magnesium stearate, stearic acid, sodium stearyl fumarate, or a combination of any two of magnesium stearate, stearic acid, and sodium stearyl fumarate; and

the optional antioxidant comprises butylated hydroxyanisole.

14. (original) The encapsulated composition according to claim 7, wherein the compound is Compound A or a sodium salt thereof; and the composition comprises from about 5 to about 80 wt.% Compound A sodium salt, from about 0.1 to about 20 wt.% nonionic surfactant, from about 0.5 to about 10 wt.% disintegrant, from 0 to about 90 wt.% diluent, from 0 to about 20 wt.% binder, from 0 to about 10 wt.% lubricant, and from 0 to about 0.1 wt.% antioxidant.

15. (original) The compressed tablet composition according to claim 10, wherein:

the compound is Compound A or a sodium salt thereof;

the nonionic surfactant comprises a poloxamer or a polysorbate;

the diluent comprises lactose, microcrystalline cellulose, or both lactose and microcrystalline cellulose;

the disintegrant comprises croscarmellose sodium, crospovidone, povidone, or sodium starch glycolate;

the lubricant comprises magnesium stearate, stearic acid, sodium stearyl fumarate, or a combination of any two of magnesium stearate, stearic acid and sodium stearyl fumarate;  
the optional binder comprises hydroxypropyl cellulose, hydroxypropyl methylcellulose, or povidone; and  
the optional antioxidant comprises butylated hydroxyanisole.

16. (original) The compressed tablet composition according to claim 10, wherein the compound is Compound A or a sodium salt thereof; and the compressed tablet comprises from about 5 to about 75 wt.% Compound A sodium salt, from about 0.1 to about 20 wt.% nonionic surfactant, from about 15 to about 90 wt.% diluent, from about 0.5 to about 10 wt.% disintegrant, from about 0.2 to about 10 wt.% lubricant, from 0 to about 10 wt.% binder, and from 0 to about 0.1 wt.% antioxidant.

17. (original) A method for preparing an encapsulated pharmaceutical composition according to claim 8, wherein the method comprises:

- (A) wet granulating a mixture of Compound A or Compound A sodium salt, the nonionic surfactant, and the disintegrant; and optionally then milling the wet granulated mixture;
- (B) drying the wet granulated mixture of Step A;
- (C) milling the dried mixture of Step B; and
- (D) encapsulating the milled mixture of Step C.

18. (original) The method according to claim 17, wherein the encapsulated composition further comprises a diluent, a lubricant, a binder, and an antioxidant; wherein the mixture employed in granulation Step A comprises Compound A or its sodium salt, the nonionic surfactant, the disintegrant, the diluent, the binder, and the antioxidant; and wherein the method further comprises lubricating the milled mixture from Step C with the lubricant prior to encapsulation in Step D.

19. (original) The method according to claim 18, wherein Compound A is employed in the form of a sodium salt; the nonionic surfactant is poloxamer; the diluent is lactose and microcrystalline cellulose; the disintegrant is croscarmellose sodium; the binder is hydroxypropyl cellulose; the lubricant is sodium stearyl fumarate; and the antioxidant is BHA.

20. (original) The method according to claim 19, wherein the encapsulated composition comprises from about 5 to about 40 wt.% Compound A sodium salt,

from about 0.5 to about 15 wt.% poloxamer 407, from about 10 to about 40 wt.% lactose, from about 10 to about 40 wt.% microcrystalline cellulose, from about 0.5 to about 5 wt.% croscarmellose sodium, from about 0.2 to about 6 wt.% sodium stearyl fumarate, from about 0.1 to about 20 wt.% hydroxypropyl cellulose; and from about 0.01 to about 0.1 wt.% BHA.

21. (original) A method for preparing a compressed tablet pharmaceutical composition according to claim 11, wherein the method comprises:

- (A) wet granulating a mixture of Compound A or Compound A sodium salt, the nonionic surfactant, diluent A, the disintegrant; and optionally then milling the wet granulated mixture;
- (B) drying the wet granulated mixture of Step A;
- (C) milling the dried mixture of Step B; and
- (D) lubricating the milled mixture of Step C with the lubricant; and
- (E) compressing the lubricated mixture of Step D into a tablet.

22. (original) The method according to claim 21, wherein the compressed tablet composition further comprises diluent B, optionally a binder, and optionally an antioxidant; and wherein the mixture employed in granulation Step A comprises Compound A or its sodium salt, the nonionic surfactant, the disintegrant, diluent A, diluent B, the binder (optional), and the antioxidant (optional).

23. (original) The method according to claim 21, wherein the compressed tablet composition further comprises diluent B, optionally a binder, and optionally an antioxidant; wherein the mixture employed in granulation Step A comprises Compound A or its sodium salt, the nonionic surfactant, the disintegrant, diluent A, the binder (optional), and the antioxidant (optional); and wherein the method further comprises blending the milled mixture of Step C with diluent B prior to lubrication in Step D.

24. (original) The method according to claim 21, wherein Compound A is employed in the form of a sodium salt; the nonionic surfactant is poloxamer; diluent A is lactose; the disintegrant is croscarmellose sodium; and the lubricant is magnesium stearate or sodium stearyl fumarate.

25. (original) The method according to claim 22, wherein Compound A is employed in the form of a sodium salt; the nonionic surfactant is poloxamer; diluent A is lactose; the disintegrant is croscarmellose sodium; the lubricant is magnesium stearate or sodium



stearyl fumarate; diluent B is microcrystalline cellulose; the binder is employed and is hydroxypropyl cellulose; and the optional antioxidant is BHA.

26. (original) The method according to claim 23, wherein Compound A is employed in the form of a sodium salt; the nonionic surfactant is poloxamer; diluent A is lactose; the disintegrant is croscarmellose sodium; the lubricant is magnesium stearate or sodium stearyl fumarate; diluent B is microcrystalline cellulose; the binder is employed and is hydroxypropyl cellulose; and the optional antioxidant is BHA.

27. (original) The method according to claim 24, wherein the compressed tablet comprises from about 10 to about 70 wt.% Compound A sodium salt, from about 0.5 to about 10 wt.% poloxamer, from about 10 to 50 wt.% lactose, from about 10 to about 50 wt.% microcrystalline cellulose, from about 0.5 to about 10 wt.% croscarmellose sodium, from about 0.2 to about 6 wt.% magnesium stearate or sodium stearyl fumarate, from about 0.5 to about 10 wt.% hydroxypropyl cellulose, and from 0 to about 0.1 wt.% BHA.

28. (original) A method for preparing a compressed tablet pharmaceutical composition according to claim 12, wherein the method comprises:

(A) freeze-drying a suspension of Compound A or its sodium salt, the nonionic surfactant, and the stabilizing agent;

(B) dry mixing the freeze-dried product of Step A with the diluent, disintegrant, and lubricant; and

(C) compressing the mixture of Step B into a tablet.

29. (original) A method for inhibiting HIV integrase in a subject in need of such inhibition, which comprises administering to the subject the pharmaceutical composition according to claim 1.

30. (original) A method for preventing or treating HIV infection or for preventing, treating or delaying the onset of AIDS in a subject in need thereof, which comprises administering to the subject the pharmaceutical composition according to claim 1.